

## § 868.5300

support and anchor a patient's breathing tube(s).

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989]

## § 868.5300 Carbon dioxide absorbent.

(a) *Identification*. A carbon dioxide absorbent is a device intended for medical purposes that consists of an absorbent material (e.g., soda lime) that is intended to remove carbon dioxide from the gases in the breathing circuit.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996]

## § 868.5310 Carbon dioxide absorber.

(a) *Identification*. A carbon dioxide absorber is a device that is intended for medical purposes and that is used in a breathing circuit as a container for carbon dioxide absorbent. It may include a canister and water drain.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996]

## § 868.5320 Reservoir bag.

(a) *Identification*. A reservoir bag is a device, usually made of conductive rubber, intended for use in a breathing circuit as a reservoir for breathing gas and to assist, control, or monitor a patient's ventilation.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996]

## § 868.5330 Breathing gas mixer.

(a) *Identification*. A breathing gas mixer is a device intended for use in conjunction with a respiratory support apparatus to control the mixing of

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gases that are to be breathed by a patient.

(b) *Classification*. Class II (performance standards).

## § 868.5340 Nasal oxygen cannula.

(a) *Identification*. A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through both nostrils.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 59 FR 63007, Dec. 7, 1994]

## § 868.5350 Nasal oxygen catheter.

(a) *Identification*. A nasal oxygen catheter is a device intended to be inserted through a patient's nostril to administer oxygen.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 59 FR 63007, Dec. 7, 1994]

## § 868.5365 Posture chair for cardiac or pulmonary treatment.

(a) *Identification*. A posture chair for cardiac or pulmonary treatment is a device intended to assist in the rehabilitation and mobilization of patients with chronic heart or lung disease.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989]

## § 868.5375 Heat and moisture condenser (artificial nose).

(a) *Identification*. A heat and moisture condenser (artificial nose) is a device intended to be positioned over a tracheotomy (a surgically created opening in the throat) or tracheal tube (a tube inserted into the trachea) to warm and humidify gases breathed in by a patient.